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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,024	11/24/2003	Grace Jones	50229-420	9113
20277 7590 02/15/2007 MCDERMOTT WILL & EMERY LLP 600 13TH STREET, N.W. WASHINGTON, DC 20005-3096			EXAMINER SHAHER, SHULAMITH H	
			ART UNIT	PAPER NUMBER
			1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/719,024

Applicant(s)

JONES ET AL.

Examiner

Shulamith H. Shafer, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 16-23 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 16-23, 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Status of Application, Amendments, And/Or Claims

The amendment received 17 December 2006 in response to the Office Action of 26 July 2006 has been entered. Claims 12-15 have been cancelled. Claims 6-9, 11, 22, and 23 have been amended and the amendments made of record. New claim 30 has been made of record. Claims 1-11, 16-23, and 30 are pending in the instant application.

The text of those sections of Title 35 U.S. Code not included in this action can be found in the prior Office action.

Withdrawn Objections/Rejections

The objection to the drawings and specification are withdrawn in view of applicants amendments to the specification and deletion of Figures 7-9.

All rejections of claims 12-15 are withdrawn. Applicants have cancelled these claims rendering all rejections of the claims moot.

The rejection of Claim 7 as vague and indefinite in that it does not recite a claim to a particular subject matter is withdrawn in view of applicants' amendment to the claim.

The rejection of claims 6, 8, and 9 as being vague and indefinite is withdrawn in view of applicants' amendment to the claims and in view of applicants withdrawal of claims 12-15 which had recited identical variant proteins with contradictory biological activities.

The rejection of Claims 22 and 23 as indefinite because Claims 22 and 23 are improper multiple dependent claims is withdrawn in view of applicants' amendment to the claims.

The rejection of Claims 6, 8, and 9 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of applicants

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cancellation of claims 12-15 which had recited identical variant proteins with contradictory biological activities.

Maintained Objections/Rejections

35 U.S.C. § 112, Second Paragraph

The rejection of Claims 1-11, and 16-23 under 35 U.S.C., second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained and applied to newly submitted claim 30 for reasons of record and for reasons set forth below.

Applicants traverse this rejection. The reasons for the traversal are:

1. Applicants have defined stringent conditions in the application
2. The specification explains how one of ordinary skill in the art would create the appropriate stringent condition.
3. The specification provides an illustrative example of stringent conditions.

Applicant's arguments have been fully considered but are not found to be persuasive for the following reasons.

Applicants' have failed to precisely claim the isolated nucleic acids encoding mutated proteins that they regard as their invention. The nucleic acids are defined as hybridizing under stringent conditions to a nucleic acid of SEQ ID NO:1. The specification teaches (page 22, line 24-27), that the "invention includes substantially identical polynucleotides that hybridize under stringent conditions ...to all or a portion of the invention's mutant receptor sequences or hormone response element sequences". The claims do not require that the variant nucleic acid hybridize over any particular length of SEQ ID NO:1, or over the full length of the molecule. The specification teaches the "hybridizing portion of the hybridizing nucleic acid is at least about 80% identical to the sequence of a portion or all of a target sequence or its complement" (page 23, lines 1-3). Thus, the broadest reasonable interpretation of the claims would encompass a myriad of nucleic acid molecules that are complementary to some portion

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of SEQ ID NO:1; this does not adequately describe the structure of the claimed nucleic acids.

The specification defines stringent conditions (page 23, lines 16-18) as those “involving hybridizing at 68 C in 5 X SSC/5X Denhart’s solution/1.0% SDS and washing in 0.2 X SSC 0.1% SDS at room temperature. Moderately stringent conditions include washing in 3 X SSC at 42 C.” The conditions recited are exemplary or illustrative, but not limiting, since the specification teaches that parameters of salt concentration and temperature may be varied to achieve optimal level of identity between the primer and the target nucleic acid. Thus, the specification (and the art) teach that the stringency of hybridization is dictated by wash and salt concentrations, and number of washes. The art recognizes that even under stringent hybridization conditions, mismatches will occur. The specification teaches (page 22, lines 29-30) “such conditions prevent hybridization of nucleic acids having 4 or more mismatches out of 20 contiguous nucleotides.....” . Therefore, the specification envisions a probability of up to 25% mismatch in hybridization under stringent conditions over 20 contiguous nucleotides of the entire target nucleic acid of SEQ ID NO:1.

The claims, as written are drawn to a genus of nucleic acids encoding proteins which are muteins of fragments of SEQ ID NO:2, as the specification teaches complementary nucleic acids sequences as those having 20 contiguous nucleotides (encoding a fragment of 7 amino acids) that are described by biological activities. Claims 1-5 and 10 require that the nucleic acids encode polypeptides which upon binding an epoxy farnesoid-like ligand results in transcriptional activation of a nuclear hormone receptor reporter construct. Claims 6-9 require that the nucleic acids encode polypeptides which upon binding an epoxy farnesoid-like ligand results in altered fluorescence with respect to the wild-type *Drosophila melanogaster* protein Ultraspiracle. Claims 11, 16-21 and 30 require that the nucleic acids encode polypeptides which upon have dominant negative nuclear hormone receptor activity. However, there are not sufficient structural limitations recited in the claims to adequately describe the claimed nucleic acids.

Therefore, given the broadest reasonable interpretation of the claims, for example:

1. Claim 1 is interpreted as comprising any isolated nucleic acid hybridizing to SEQ ID NO:1 under any conditions encoding a protein comprising two tryptophan residues two amino acid residues apart which exhibits the recited functional activity
2. Claims 2-5 are interpreted as comprising any isolated nucleic acid hybridizing under any conditions to SEQ ID NO:1 encoding a protein comprising one tryptophan residue which exhibits the recited functional activity.
3. Claims 6 and 7 are interpreted as comprising any isolated nucleic acid hybridizing to SEQ ID NO:1 under any conditions encoding a protein comprising one phenylalanine residue which exhibits the recited functional activity.
4. Claim 8 is interpreted as comprising any isolated nucleic acid hybridizing to SEQ ID NO:1 under any conditions encoding a protein comprising two phenylalanine residues ten amino acid residues apart which exhibits the recited functional activity.

Claims 1-11, 16-23, and 30 are drawn to nucleic acid molecules (which hybridize to SEQ ID NO:1, the hybridizing portion of the hybridizing nucleic acid being at least 80% identical to the sequence of a portion or all of a target sequence (page 23, lines 1-3)) and the variant proteins these nucleic acid molecules encode. The nucleic acid of SEQ ID NO:1 encodes the polypeptide of SEQ ID NO:2, the Ultraspiracle protein which is well known in the art (see, for example, 1990. Oro et al. Nature 347:298-301, cited in previous office action).

It is suggested the claims (1-11, 16-21 and 30) be rewritten as, for example: "An isolated nucleic acid encoding a protein of SEQ ID NO:2 except having a X residue in a first position corresponding to position Y of SEQ ID NO:2 and an A residue in a second position corresponding to position B of SEQ ID NO:2 which protein activates transcription of a nuclear hormone receptor reporter construct upon binding an epoxy farnesoid-like ligand".

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Conclusion:

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SHS



LORRAINE SPECTOR
PRIMARY EXAMINER